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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,407	FAIRLIE ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *102-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *102-160* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) claims 102-116 and 151, drawn to a compound having a plurality of alpha helical cyclic pentapeptide sequences, which is represented by formula (IV).

Group 2, claim(s) 141, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-1,5)-[KARAD]-NH_2 (SEQ ID NO: 8) or AC-(cyclo-1,5)-[KARAD]-OH (SEQ ID NO: 20) or H-(cyclo-1,5)-[KARAD]-NH_2 (SEQ ID NO: 21) or H-(cyclo-1,5)-[KARAD]-OH (SEQ ID NO: 22).

Group 3, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is AcR-(cyclo-2,6)-[KLLLD]-NH_2.

Group 4, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is AcR-(cyclo-2,6)-[KLALD]-NH_2.

Group 5, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is AcR-(cyclo-2,6)-[KLFAD]-NH_2.

Group 6, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is AcR-(cyclo-2,6)-[KLALD]-NH_2.

Group 7, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KAAAD]-NH_2.

Group 8, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KALAD]-NH_2.

Group 9, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KAMAD]-NH_2.

Group 10, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KAQAD]-NH_2.

Group 11, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KAFAD]-NH_2.

Group 12, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KAGAD]-NH_2.

Group 13, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KGSAD]-NH_2.

Group 14, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KSSSD]-NH_2.

Group 15, claim(s) 141 and 151, drawn to a compound having the formula (I), wherein the compound is Ac-(cyclo-2,6)-[KGGGD]-NH_2.

Group 16, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide according to formula (IV), and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 17, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-1,5)-[KARAD]-NH_2 (SEQ ID NO: 8) or AC-(cyclo-1,5)-[KARAD]-OH (SEQ ID NO: 20) or H-(cyclo-1,5)-[KARAD]-NH_2 (SEQ ID NO: 21) or H-(cyclo-1,5)-[KARAD]-OH (SEQ ID NO: 22), and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 18, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide AcR-(cyclo-2,6)-[KLLLD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 19, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide AcR-(cyclo-2,6)-[KLALD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 20, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide AcR-(cyclo-2,6)-[KLFAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 21, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KAAAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 22, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KALAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 23, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KAMAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 24, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KAQAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 25, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KAFAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 26, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KAGAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 27, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KGSAD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 28, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KSSSD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 29, claim(s) 142-146, drawn to a method for constructing a constrained helical peptide, the method comprising (1) synthesizing a peptide Ac-(cyclo-2,6)-[KGGGD]-NH_2, and (2) cyclizing the peptide by linking the side chain of the first terminal residue with the side chain of the second terminal residue.

Group 30, claim(s) 147-150, drawn to a method of producing a mimic of an alpha helical binding determinant comprising, providing a protein of interest that comprises an alpha helical domain that interacts with a ligand, identifying a candidate binding determinant situated within a sequence of 3 or more contiguous amino acid residues in the helical binding domain, and selecting a first residue and a second residue in The sequence which are separated by an intervening sequence of 3 amino acid residues.

Group 31, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-Y[KRELD][KMADD]F (SEQ ID NO: 57).

Group 32, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-V[KRQLD][KIADD]I (SEQ ID NO: 58).

Group 33, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-I[KAQED][KVADD]M (SEQ ID NO: 59).

Group 34, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-I[KRELD][KIADD]F (SEQ ID NO: 60).

Group 35, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-3-(4-hydroxyphenyl)-propionyl[KRELD][KMADD] phenethylamide (SEQ ID NO: 61).

Group 36, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-iso-valeroyl[KRQLD][KIADD]2-methylbutylamide (SEQ ID NO: 62).

Group 37, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-3-methylpentanoyl-[KAQED][KVADD]-3-methylsulfanyl-propylamide (SEQ ID NO: 63).

Group 38, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein

the compound is a BH3 domain mimetic and is cyclo(2-6,7-11)-3-methylpentanoyl-[KAQED][KIADD]-phenethylamide (SEQ ID NO: 64).

Group 39, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(3,7)-LA[KVADD]F (SEQ ID NO: 65).

Group 40, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(3,7)-LA[KIAAD]I (SEQ ID NO: 66).

Group 41, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(3,7)-LA[KVADD]I (SEQ ID NO: 67).

Group 42, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is cyclo(3,7)-LA[KIADD]F (SEQ ID NO: 68).

Group 43, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is Cyclo(2,6)-7-methyl octanoyl-[KMADD]-Phenethylamide (SEQ ID NO: 69).

Group 44, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is Cyclo(2,6)-7-methyl octanoyl-[KIADD]-2-methylbutylamide (SEQ ID NO: 70).

Group 45, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is Cyclo(2,6)-7-methyl octanoyl-[KVADD]-2-methylbutylamide (SEQ ID NO: 71).

Group 46, claim(s) 156, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a BH3 domain mimetic and is Cyclo(2,6)-7-methyl octanoyl-[KMADD]-Phenethylamide (SEQ ID NO: 72).

Group 47, claim(s) 157, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein

the compound is a p53 tumor suppressor mimetic and is Cyclo(3,7)-FM[K(Pmp)(6ClW)ED]L (SEQ ID NO: 73).

Group 48, claim(s) 157, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a p53 tumor suppressor mimetic and is Cyclo(3,7)-3-Penylheptanoyl-M[K(Pmp)(6ClW)ED]isopentylamide (SEQ ID NO: 74).

Group 47, claim(s) 157, drawn to a method for treating or preventing a disease or condition related to an aberration in apoptosis regulation or tumor suppression, wherein the compound is a p53 tumor suppressor mimetic and is Cyclo(2,6)-6-Penylheptanoyl[K(Pmp)(6ClW)ED]isopentylamide (SEQ ID NO: 75).

Group 48, claim(s) 160, drawn to a method for treating or preventing a disease or condition related to pain transmission, anxiety, appetite, alcohol withdrawal, opiate withdrawal epilepsy or memory, wherein the compound is Cyclo(6-10,11-15)-FGGFT[KARKD][KRKLD]NH_2 (agonist) (SEQ ID NO: 76).

Group 49, claim(s) 160, drawn to a method for treating or preventing a disease or condition related to pain transmission, anxiety, appetite, alcohol withdrawal, opiate withdrawal epilepsy or memory, wherein the compound is Cyclo(6-10,11-15)-NpheGGFT[KARKD][KRKLD]NH_2 (antagonist) (SEQ ID NO: 77).

Group 50, claim(s) 160, drawn to a method for treating or preventing a disease or condition related to pain transmission, anxiety, appetite, alcohol withdrawal, opiate withdrawal epilepsy or memory, wherein the compound is Cyclo(2-6,7-11)-Ac-T[KARKD][KRKLD]NH_2 (antagonist) (SEQ ID NO: 78).

Group 51, claim(s) 160, drawn to a method for treating or preventing a disease or condition related to pain transmission, anxiety, appetite, alcohol withdrawal, opiate withdrawal epilepsy or memory, wherein the compound is Cyclo(2-6,7-11)-(8-napthalen-1-yl-methyl-4-oxo-1-phenyl-1,3,8-traiza-spiro[4,5]dec-3-yl)-acetoyl-[KARKD][KRKLD]NH_2 (antagonist) (SEQ ID NO: 79).

Linking Claims

2. Claims 117-140 link(s) inventions 2 through 15. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 117-142. Claims 152-155 link(s) inventions 31 through 47. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking

claim(s), claims 152-155. Claims 152-153, 158-159 link(s) inventions 48 through 51. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 152-153, 158-159. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. The inventions listed as Groups 1 through 51 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The compounds are patentably independent and distinct because the amino acid contents are different, and thus structures are different. The peptide sequences are different and therefore, each sequence is structurally distinct. There is no common structure present. For example, Formula (IV) is a cyclic pentapeptide sequence, wherein p is an integer from 2 to 4; Formula I is a cyclic peptide having no repeating units. Furthermore, an amino acid sequence KARAD is patentably independent and distinct from KSSSD.

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)

(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)

(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Election of Species

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different compounds of formula (IV) due to different variables;

Different compounds of formula (I) due to different variables;

Different disease or conditions.

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner:

Claims 106, 108-111, 116, 119-121, 125, 128-132, 135, 138-140, 153-155, 158-159.

The following claim(s) are generic: 102-105, 107, 112-115, 117-118, 122-124, 126, 133-134, 136-137, 141-152, 156-157, 160.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The different compound of formula (IV) are patentably independent and distinct due to their different amino acid content and variables leading to different structures. For example, a peptide having the sequence RQAGD (any amino acid sequence) is patentably different from the sequence KARAD. Further, search for one would not necessarily lead to the other. A compound having the structure cyclo(1-5,6-10)-Ac-[KARADKARAD]-NH_2 would not necessarily lead to a structure cyclo(1-5,6-10,11-15)-Ac-[KARADKARADKARAD]-NH_2, leading to different search. Different compounds of formula (I) are patentably independent and distinct due to their different amino acid content and variables leading to different structures. For example, a peptide having the sequence RQAGD (any amino acid sequence) is patentably different from the sequence KARAD. Further, search for one would not necessarily lead to the other. Different diseases or conditions are

patentably independent and distinct due to different cells and mechanisms involved. For example, tumor suppression involves tumor cells; epilepsy is a group of related disorders characterized by a tendency for recurrent seizures (see http://www.webmd.com/epilepsy/default.htm). A person suffering from tumor (cancer), anxiety, appetite would not necessarily suffer from epilepsy, and vice versa. A search for one would not necessarily lead to the other.

10. If Group 1 is elected, Applicant is required to elect a single disclosed species of a compound of formula (IV) wherein all of the variables are elected to arrive at a single disclosed species of a compound of formula (IV). For example, Applicant elects Group 1, and elects the compound cyclo(1-5,6-10)-Ac-[KARADKARAD]-NH_2 (SEQ ID NO: 46). If any group is elected from Groups 2-15, Applicant is required to elect a single disclosed species of a compound of formula (I) wherein all of the variables are elected to arrive at a single disclosed species of a compound of formula (I). For example, Applicant elects Group 2, and elects Ac-(cyclo-1,5)-[KARAD]-NH_2 (SEQ ID NO: 8). If any Group is elected from Groups 31-51, Applicant is required to elect a single disclosed species of a disease or disorder. For example, Applicant elects Group 50, and elects, epilepsy.

11. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

12. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

13. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence**

now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

15. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654